

## **Zealand Pharma announces progress to Phase 3 with dasiglucagon for the treatment of congenital hyperinsulinism in first half 2018**

- Zealand receives FDA approval of its Investigational New Drug (IND) application for its Phase 3 program with dasiglucagon for treatment of congenital hyperinsulinism (CHI)
- Two Phase 3 trials are set to start within the coming months at leading centers in the U.S. and Europe
- Zealand expects fast development progress to ultimately offer an effective non-surgical treatment for this rare disease affecting neonates and children
- U.S. FDA and the European Commission have already granted orphan drug designation for dasiglucagon for the treatment of CHI in 2017

*Copenhagen, Denmark, January 19, 2018* – The U.S. Food and Drug Administration (FDA) has approved Zealand's Investigational New Drug (IND) application for initiation of two Phase 3 clinical trials of dasiglucagon in CHI. This positive regulatory milestone and the current clinical evidence enable Zealand to proceed directly into Phase 3 development of dasiglucagon for the treatment of CHI.

CHI is a rare medical condition in neonates and children. Due to a genetic defect in the insulin producing cells, these children are born with too high blood insulin levels, resulting in persistent low blood glucose throughout childhood. Current treatment options are insufficient and the most severely affected children have the pancreas surgically removed within the first months of life in order control the blood glucose levels.

In the Phase 3 program, Zealand will evaluate the potential of chronic dasiglucagon infusions delivered via a pump to prevent hypoglycemia in up to 50 children with CHI and thereby reduce morbidities associated with persistent hypoglycemia as well as neurodevelopmental defects and need for pancreatectomy

Dasiglucagon is a potential first-in-class glucagon analog invented and developed by Zealand. It is stable in aqueous formulation and suitable for pump use and thereby for potential treatment of (CHI). In 2017, the U.S. FDA and the European Commission both granted orphan drug designation for dasiglucagon for the treatment of CHI.

### **Britt Meelby Jensen, President and CEO of Zealand, comments:**

*"Congenital hyperinsulinism is a rare and severe disease, which affects newborns and children. I am very pleased with FDA's decision to approve our Phase 3 trials, as it allows us to make fast progression towards a potential treatment that can help these children and possibly save them from surgery with severe lifelong implications"*

### **Dasiglucagon is in development for use in other indications**

Dasiglucagon is in development for two additional indications:

- Rescue treatment of severe hypoglycemia: Two Phase 3 trials ongoing in patients with type 1 diabetes for treatment in a ready-to-use rescue pen, with results expected in 2018.



- Treatment of Type 1 Diabetes in a dual-hormone artificial pancreas pump containing both insulin and glucagon (dasiglucagon), with potential to bring a paradigm shift in treatment. Positive results reported from two Phase 2a studies in 2017, and a Phase 2b proof-of-concept trial is planned for 2018.

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**About Zealand Pharma A/S**

Zealand Pharma A/S (Nasdaq Copenhagen and New York: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, design and development of innovative peptide-based medicines. Zealand has a portfolio of medicines and product candidates under license collaborations with Sanofi and Boehringer Ingelheim, and a late stage pipeline of internal product candidates focusing on specialty gastrointestinal and metabolic diseases.

Zealand is based in Copenhagen (Glostrup), Denmark. For further information about the Company's business and activities, please visit [www.zealandpharma.com](http://www.zealandpharma.com) or follow Zealand on LinkedIn or Twitter @ZealandPharma.